

EXHIBIT 4

2003 U.S. Dist. LEXIS 10098, *

NOVO NORDISK A/S and NOVO NORDISK PHARMACEUTICALS, INC., Plaintiffs, v. BIO-TECHNOLOGY GENERAL CORP., LTD. and TEVA PHARMACEUTICALS USA, INC., Defendants.

Civil Action No. 02-332-SLR

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

2003 U.S. Dist. LEXIS 10098

June 9, 2003, Decided

PRIOR HISTORY: Novo Nordisk A/S v. Bio-Technology Gen. Corp., 52 Fed. Appx. 142, 2002 U.S. App. LEXIS 25389 (2002)

DISPOSITION: [*1] Plaintiffs' motion for summary judgment that defendants' invalidity claims were barred by judicial estoppel was denied. Defendants' motion for summary judgment that their invalidity claims were not barred by judicial estoppel was granted. Defendants' motion for summary judgment that claims of patent in suit were not entitled to filing date of plaintiffs' 1983 PCT application under doctrine of judicial estoppel was denied. Plaintiffs' motion for summary judgment that they were not estopped from claiming benefit of filing date of 1983 PCT action was denied.

CASE SUMMARY


PROCEDURAL POSTURE: Plaintiff patent holders sued defendants, a patent applicant and its licensee, for patent infringement. The parties filed cross-motions for summary judgment as to the applicability of judicial estoppel.

OVERVIEW: The applicant filed a patent application for a form of human growth hormone. In order to provoke an interference with the holders' human growth hormone patent, the applicant copied claims from the holders' patent into its application. The United States Patent and Trademark Office's Board of Patent Appeals and Interferences declared an interference and entered judgment in the holders' favor. The holders argued that defendants' invalidity claims were barred by judicial estoppel, but defendants' position in the infringement action was not irreconcilably inconsistent with the applicant's copying of the claims into its application; ownership, not validity, was the focus of the interference proceedings, and neither position was arrived at in bad faith. Defendants argued that the patent claims should not be entitled to the filing date of the holders' 1983 PCT action due to judicial estoppel, as the holders had allegedly made inconsistent statements concerning the process in the 1983 PCT application. The court found that factual issues precluded summary judgment on that point for either party.

OUTCOME: Defendants' motion for summary judgment that their invalidity claims were not barred by judicial estoppel was granted, and the holders' motion for summary judgment barring the invalidity claims was denied. As to the filing date issue, both the holders' and defendants' summary judgment motions were denied.


CORE TERMS: patent, judicial estoppel, summary judgment, invalidity, estopped, patentable, subject matter, filing date, foreign patent, provoke, invalid, copied, present litigation, nonmoving party, moving party, irreconcilably, defendants contend, examiner, weighs, contradictory, ownership, entitled to judgment, judicial process, burden of proof, present action, genuine issue, material fact, matter of law, specification, patentability

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HN1 ⚡ A court shall grant summary judgment only if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c). The moving party bears the burden of proving that no genuine issue of material fact exists. Facts that could alter the outcome are "material," and disputes are "genuine" if evidence exists from which a rational person could conclude that the position of the person with the burden of proof on the disputed issue is correct. [More Like This Headnote](#)

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HN2 ⚡ If the party moving for summary judgment has demonstrated an absence of material fact, the nonmoving party then must come forward with specific facts showing that there is a genuine issue for trial. Fed. R. Civ. P. 56(e). The court will view the underlying facts and all reasonable inferences therefrom in the light most favorable to the party opposing the motion. The mere existence of some evidence in support of the nonmoving party, however, will not be sufficient for denial of a motion for summary judgment; there must be enough evidence to enable a jury reasonably to find for the nonmoving party on that issue. [More Like This Headnote](#)

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HN3 ⚡ Upon a summary judgment motion, if the nonmoving party fails to make a sufficient showing on an essential element of its case with respect to which it has the burden of proof, the moving party is entitled to judgment as a matter of law. [More Like This Headnote](#)

[Civil Procedure](#) > [Preclusion & Effect of Judgments](#) > [Judicial Estoppel](#) 

HN4 ⚡ Judicial estoppel is a non-patent related procedural issue and, therefore, is applied in accordance with the law of the regional circuit as opposed to Federal Circuit law. The doctrine of judicial estoppel is an equitable doctrine invoked by a court at its discretion. [More Like This Headnote](#)

[Civil Procedure](#) > [Preclusion & Effect of Judgments](#) > [Judicial Estoppel](#) 

HN5 ⚡ The judicial estoppel doctrine is intended to prevent parties from playing "fast and loose" with the courts and, in the Third Circuit, entails a three-part inquiry: (1) the party to be estopped must have taken two positions that are irreconcilably inconsistent; (2) the party must have changed its position in bad faith; and (3) judicial estoppel must be tailored to address the harm

identified and no lesser sanction would adequately remedy the damage done by the litigant's misconduct. [More Like This Headnote](#)

[Patent Law](#) > [U.S. Patent & Trademark Office Prosecution Procedures](#) > [Interferences](#)

HNG 37 C.F.R. § 1.607(a) does not require a party seeking an interference to affirmatively represent that claims it has copied from an issued patent into its application are valid; rather, the fact that the claims issued in a patent raises a presumption of validity. [More Like This Headnote](#)

[Patent Law](#) > [Infringement](#) > [Defenses](#) > [Invalidity](#)

HNZ There is a strong public policy interest in removing invalid patents from the marketplace. [More Like This Headnote](#)

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JUDGES: Sue L. Robinson, United States District Judge.

OPINIONBY: Sue L. Robinson

OPINION: MEMORANDUM OPINION

Dated: June 9, 2003

Wilmington, Delaware

ROBINSON, Chief Judge

I. INTRODUCTION

In this patent infringement suit, plaintiffs Novo Nordisk Pharmaceuticals, Inc. and Novo Nordisk A/S (collectively, "Novo") have accused defendants Bio-Technology General Corp. ("BTG") and Teva Pharmaceuticals USA, Inc. ("Teva") of infringing United States Patent No. 5,633,352 ("the '352 patent") through defendants' activities involving the Tev-Tropin TM brand human growth hormone ("hGH"). This court has jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a).

Presently before the court is plaintiffs' motion for summary judgment that defendants' invalidity claims are barred by judicial estoppel and defendants' related motion for summary judgment that their invalidity claims are not barred by judicial estoppel. (D.I. 86, 98) Also before the court is defendants' motion for summary judgment that the claims of the patent in suit are not entitled to the filing date of plaintiffs' 1983 PCT application under the doctrine of judicial estoppel and plaintiffs' related motion for summary judgment that they are not

estopped from [*3] claiming the benefit of the filing date of the 1983 PCT action. (D.I. 116, 146)

II. BACKGROUND

Plaintiffs' '352 patent entitled "Biosynthetic Human Grown Hormone" issued on May 27, 1997. On February 13, 1998, BTG filed an application for a patent in the Patent Office entitled "Bacterially Derived Authentic Human Growth Hormone." In order to provoke an interference with Novo's '352 patent, BTG copied claims from the '352 patent into its application. Consequently, the Board of Patent Appeals and Interferences of the United States Patent and Trademark Office (the "Board") declared an interference between BTG's application and the '352 patent on July 7, 2000. On March 12, 2002, the Board entered a Decision on Preliminary Motions and Final Judgment adverse to BTG and in favor of Novo. Subsequently, plaintiffs filed the present action against BTG and its exclusive licensee Teva, for infringement of the '352 patent. In an action related to the present case, BTG is appealing the decision of the Board to this court pursuant to 35 U.S.C. § 146.

III. STANDARD OF REVIEW

HN1 ¶ A court shall grant summary judgment only if "the pleadings, depositions, answers [*4] to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). The moving party bears the burden of proving that no genuine issue of material fact exists. See Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 586 n.10, 89 L. Ed. 2d 538, 106 S. Ct. 1348 (1986). "Facts that could alter the outcome are 'material,' and disputes are 'genuine' if evidence exists from which a rational person could conclude that the position of the person with the burden of proof on the disputed issue is correct." Horowitz v. Fed. Kemper Life Assurance Co., 57 F.3d 300, 302 n.1 (3d Cir. 1995) (internal citations omitted).

HN2 ¶ If the moving party has demonstrated an absence of material fact, the nonmoving party then "must come forward with 'specific facts showing that there is a genuine issue for trial.'" Matsushita, 475 U.S. at 587 (quoting Fed. R. Civ. P. 56(e)). The court will "view the underlying facts and all reasonable inferences therefrom in the light most favorable to the party opposing the motion." Pa. Coal Ass'n v. Babbitt, 63 F.3d 231, 236 (3d Cir. 1995). [*5] The mere existence of some evidence in support of the nonmoving party, however, will not be sufficient for denial of a motion for summary judgment; there must be enough evidence to enable a jury reasonably to find for the nonmoving party on that issue. See Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 249, 91 L. Ed. 2d 202, 106 S. Ct. 2505 (1986).

HN3 ¶ If the nonmoving party fails to make a sufficient showing on an essential element of its case with respect to which it has the burden of proof, the moving party is entitled to judgment as a matter of law. See Celotex Corp. v. Catrett, 477 U.S. 317, 322, 91 L. Ed. 2d 265, 106 S. Ct. 2548 (1986).

IV. DISCUSSION

A. The Parties' Summary Judgment Motions Regarding Judicial Estoppel With Respect to Invalidity

HN4 ¶ Judicial estoppel is a non-patent related procedural issue and, therefore, is applied in accordance with the law of the regional circuit as opposed to Federal Circuit law. See Lampi

Corp. v. American Power Prods., 228 F.3d 1365, 1376 (Fed. Cir. 2000). "The doctrine of judicial estoppel is an equitable doctrine invoked by a court at its discretion." McNemar v. Disney Store, 91 F.3d 610, 617 (3d Cir. 1996). The purpose of the doctrine [*6] is to protect the integrity of the courts and the judicial process. Id. at 616-17.

HNS The doctrine is intended to prevent parties from playing "fast and loose" with the courts and, in the Third Circuit, entails a three-part inquiry: (1) the party to be estopped must have taken two positions that are irreconcilably inconsistent; (2) the party must have changed its position in bad faith; and (3) judicial estoppel must be "tailored to address the harm identified" and no lesser sanction would adequately remedy the damage done by the litigant's misconduct. Montrose Med. Group Participating Sav. Plan v. Bulger, 243 F.3d 773, 779-80 (3d Cir. 2001).

In the case at bar, plaintiffs argue that defendants should be judicially estopped from asserting invalidity claims against the '352 patent based on the contentions defendants made to the Board and prior art they failed to raise in the related interference proceedings. In support of their argument, plaintiffs contend that defendants' positions in the interference and in the present litigation are "diametrically opposed." (D.I. 87 at 27)

1. Plaintiffs' assertions.

Plaintiffs assert that in order to provoke [*7] the interference, BTG copied claims from the '352 patent into its application and stated to the examiner that these claims were patentable. Throughout the interference proceedings, BTG never raised the issue of invalidity to the Board nor supplied it with the prior art it alleges invalidates the claims (the "Genentech prior art"). According to plaintiffs, if BTG had thought that this prior art was material to the patentability of the claims, it had a duty to disclose it under 37 C.F.R. § 1.56. Defendants' contentions at bar that these claims are invalid is contrary to BTG's explicit and implicit representations to the Board and, therefore, the first prong of the Montrose inquiry is satisfied.

Next, plaintiffs argue that defendants' contradictory positions are proffered in bad faith. In support of this argument, plaintiffs contend that defendants were well aware of the Genentech prior art during the interference proceedings but failed to raise it then because it did not further their purposes. If defendants had told the examiner that the claims were not patentable over the Genentech prior art, the interference would not have been declared and their ability [*8] to obtain those claims would have been stymied.

Additionally, plaintiffs argue that defendants' appeal of the Board's decision further evidences their bad faith. While defendants attack the validity of the claims in the present action, they are claiming the right to those claims in the related action. These contradictory positions could lead to inconsistent results between the present litigation and related § 146 appeal which would be an affront to the integrity of this court. As such, defendants' bad faith is evident and the second prong of the Montrose inquiry is satisfied. This type of activity is exactly the type of conduct the doctrine of judicial estoppel is meant to curtail.

Furthermore, the doctrine should apply equally to Teva even though it was not a party to the interference because Teva was in privity with BTG, as its exclusive licensee, prior to the interference action. Applying the doctrine to both defendants is the only way to protect the integrity of the court. Therefore, precluding defendants from raising claims of invalidity of the '352 patent is narrowly "tailored to address the harm identified" as set forth in Montrose.

2. Defendants' responses. [*9]

In response to plaintiffs' allegations, defendants proffer a number of arguments and move for summary judgment that they are not estopped from raising an invalidity defense. First, defendants assert that the positions they took during the interference and now are not "irreconcilably inconsistent." BTG never told the Patent Office that the subject matter claimed in the '352 patent was patentable over any prior art, much less the Genentech prior art. Rather, BTG's statements merely told the examiner that the claims of the '352 patent in its application were supported by the specification of BTG's application. Furthermore, the language used by BTG was essentially a quote from 35 U.S.C. § 135 (b) in order to provoke the interference. In provoking the interference, BTG was not stating that the claims in its application were patentable over the prior art, rather, BTG was stating that it was the owner of the subject matter of those claims. In fact, 37 C.F.R. § 1.607 (a), which sets forth the required showing to provoke an interference, does not require that a party seeking an interference even represent that its claims are patentable. Defendants contend that plaintiffs' [*10] argument asks this court to read inferences into its statements that are not there.

Next, defendants argue that their conduct was not in bad faith in either proceeding. In support of this argument, defendants contend that plaintiffs submitted no evidence of bad faith, rather, again they ask the court to infer such conduct. There is no evidence that BTG undertook an analysis of the Genentech prior art prior to provoking the interference and was not focused on validity issues at the time but, rather, ownership of the subject matter. Furthermore, any change in defendants' position with respect to some of the Genentech prior art was due to an intervening Federal Circuit decision; a litigant is not required to maintain a position that has been rejected by a court merely for consistency's sake. Where circumstances have changed since the prior proceeding, judicial estoppel is not appropriate. In fact, BTG has shown good faith by bringing this court decision to the attention of the Board during the interference.

Defendants also argue that BTG was not required to, nor did it, make any patentability representations to the Board during the interference proceedings. Neither party raised the issue [*11] of whether or not the subject matter claimed in the '352 patent was patentable over the Genentech prior art. Although BTG did submit the Federal Circuit's decision regarding some of the prior art to the Board, the Board declined to address whether or not the subject matter claimed in the '352 patent was patentable over the Genentech prior art.

Next, defendants argue that applying judicial estoppel in this case would be overbroad and harm Teva and the public at large. First, defendants contend that Teva was never in privity with BTG for judicial estoppel purposes since it never had the relationship with BTG that gives rise to such a remedy. Next, defendants argue that the strong public policy in favor of removing invalid patents from the marketplace outweighs any perceived harm to plaintiffs or alleged misconduct by defendants.

3. Analysis.

"The doctrine of judicial estoppel is an equitable doctrine invoked by a court at its discretion." McNemar, 91 F.3d at 617. Under the facts of record, the court declines to invoke the doctrine. With respect to the first factor of the Montrose inquiry, the court finds that defendants' two positions, while somewhat at [*12] odds, are not irreconcilably inconsistent. During the interference proceedings, the parties were not focused on invalidity issues but, rather, on who owned the subject matter of the '352 claims. BTG copied the

claims of the '352 patent into its application to provoke the interference, as is standard practice. This is the procedure the Patent Office provides for parties to settle ownership disputes. BTG did not draft or prosecute the claims it copied into its application, rather, it merely inserted them to invoke the interference procedure. In sum, incorporating the claims of the '352 patent in its application was not necessarily an endorsement of the validity of the claims previously deemed patentable in the '352 patent, but simply a formality in invoking the interference. n1 Therefore, defendants' invalidity contentions at bar are not directly inconsistent with any affirmative representations made to the Board. n2

- - - - - Footnotes - - - - -

n1 37 C.F.R. § 1.607(a) ~~HNG~~ does not require a party seeking an interference to affirmatively represent that claims it has copied from an issued patent into its application are valid, rather, the fact that the claims issued in a patent raises a presumption of validity. [*13]

n2 The court notes, however, that if defendants are successful in proving the claims of the '352 patent are invalid, they will be bound by that determination and its ramifications in their related § 146 appeal from the Board.

- - - - - End Footnotes - - - - -

Turning to the second factor of the Montrose inquiry, the court concludes that neither of defendants' two positions were arrived at in bad faith. As discussed above, even though BTG may have had the Genentech prior art in its possession during the interference proceedings, it had no motivation to analyze it with an eye towards the invalidity of the '352 claims since the issue of interest was ownership of the subject matter. As such, the court finds that defendants did not improperly withhold these references or its invalidity arguments in bad faith. Additionally, as the court has concluded that defendants' two positions are not irreconcilably inconsistent, they have not raised the invalidity claims in the present litigation in bad faith. Therefore, the second Montrose factor weighs against applying judicial estoppel.

Finally, the court concludes that the third [*14] factor of the Montrose inquiry also weighs in favor of not applying the doctrine to the case at bar. ~~HNZ~~ There is a strong public policy interest in removing invalid patents from the marketplace. Such patents improperly stifle competition and remove from the public what rightly belong to it. Thus, the policy interest in allowing defendants to test the validity of the '352 patent outweighs any prejudice plaintiffs may suffer in defending their patent. Defendants still face the arduous task of proving by clear and convincing evidence that the '352 patent is invalid and, as discussed above, will be bound by that determination in the related case. This remedy is more narrowly tailored to achieve equity in the present case.

In conclusion, the court finds that upon balancing the factors, the Montrose inquiry weighs against applying the doctrine of judicial estoppel to the present case. Not applying the doctrine here does not erode the integrity of the courts or the judicial process. Therefore, plaintiffs' motion for summary judgment is denied and defendants' motion is granted.

B. The Parties' Summary Judgment Motions Regarding Judicial Estoppel With Respect to Priority

Not to [*15] be outdone by plaintiffs, defendants have filed their own motion for summary judgment that the claims of the '352 patent are not entitled to the filing date of plaintiffs' 1983 PCT application under the doctrine of judicial estoppel. Although styled as a single motion, defendants actually seek a number of rulings that would "almost certainly dispose of the entire case." (D.I. 117 at 1)

1. Defendants' assertions.

Defendants first seek a ruling that plaintiffs are judicially estopped from claiming that the process in its 1983 PCT application yields 191-Amino Acid hGH. In support of this argument, defendants contend that plaintiffs told at least two foreign patent offices (the EPO and Canadian Patent Office) that the process in the 1983 PCT application did not yield 191-Amino Acid hGH, resulting in the issuance of foreign counterparts of the '352 patent. However, in prosecuting the application of the '352 patent in the United States, plaintiffs claimed priority to the 1983 PCT application arguing that it did yield 191-Amino Acids, as required by the claims of the '352 patent. Defendants argue that this "flip-flop" in positions allowed plaintiffs to claim priority to the 1983 PCT [*16] application, antedate a number of prior art references, and ultimately lead to the issuance of the '352 patent.

Plaintiffs also maintained this position with the Board during its interference proceedings which led to the Board awarding plaintiffs priority over defendants. In sum, defendants contend that the position plaintiffs are taking now with respect to the '352 patent are diametrically opposed to the positions they took at the EPO and Canadian Patent Office. Furthermore, these contradictory positions were knowingly taken in bad faith in order to achieve plaintiffs' desired results before each panel.

Based on this position, defendants next ask this court for a ruling that the claims of the '352 patent are not entitled to claim priority to the 1983 PCT application. In support of this argument, defendants assert that since plaintiffs may no longer argue that the 1983 PCT application yields 191-Amino Acid hGH, the specification no longer enables the claims of the '352 patent because they are both directed to 191-Amino Acid hGH. Since the claims of the '352 patent are not enabled by the 1983 PCT application, they may not claim priority from it.

Finally, defendants ask the court [*17] for a ruling that plaintiffs are judicially estopped from contending that the 1983 PCT application teaches the use of charged amino acids. Again defendants assert that this argument by plaintiffs now would be directly contrary to plaintiffs' position before the EPO.

2. Plaintiffs' responses.

In response to these allegations, plaintiffs make a number of arguments and, not surprisingly, move for summary judgment that they are not judicially estopped from claiming priority from the 1983 PCT application. Plaintiffs first argue that the doctrine of judicial estoppel is inapplicable to prior statements made in foreign proceedings related to foreign patent applications governed by foreign law. Since foreign patent proceedings related to foreign patent applications are not binding on issues of validity under United States patent law, statements made by a party's foreign patent counsel in foreign proceedings cannot possibly be determinative of validity issues in the U.S.

Next, plaintiffs argue that defendants are precluded from seeking the relief sought in their motion because this argument was presented and rejected by the Board in the interference proceedings. Therefore, defendants [*18] are collaterally estopped from re-litigating the issue here. Their proper remedy is the § 146 appeal which is concurrently pending with this litigation, not a reargument on the merits in the present case.

Finally, plaintiffs argue that the statements made in the foreign patent proceedings are not inconsistent with their positions in the interference and the present litigation. In support of this argument, plaintiffs paint a different picture of the facts and statements and argue that the 1983 PCT application does enable the claims of the '352 patent.

3. Analysis.

Upon review of the record presented by the parties, the court concludes that summary judgment granting either plaintiffs' or defendants' requested relief is improper and, therefore, both parties' summary judgment motions are denied. Given the complex and highly factual nature of the inquiry along with the fact that both cases (the present litigation and defendants' § 146 appeal) will be tried concurrently to the court, granting summary judgment to either party would be premature and not based on the fullest available record. Both parties' requests are laced with questions of subjective intent, bad faith, and conflicting [*19] accounts of the facts. Furthermore, to effectively rule on the parties' motions would require the court to engage in an enablement analysis, a subject that has not been properly posed to the court by way of motion. Therefore, the court concludes that there are genuine issues of material fact in both parties' motions and declines to address these issues on summary judgment.

V. CONCLUSION

For the reasons stated, plaintiffs' motion for summary judgment that defendants' invalidity claims are barred by judicial estoppel is denied and defendants' motion for summary judgment that their invalidity claims are not barred by judicial estoppel is granted. Additionally, defendants' motion for summary judgment that the claims of the patent in suit are not entitled to the filing date of plaintiffs' 1983 PCT application under the doctrine of judicial estoppel is denied and plaintiffs' motion for summary judgment that they are not estopped from claiming the benefit of the filing date of the 1983 PCT action is denied. An appropriate order shall issue.

ORDER

At Wilmington this 9th day of June, 2003, consistent with the memorandum opinion issued this same day;

IT IS ORDERED that: [*20]

1. Plaintiffs' motion for summary judgment that defendants' invalidity claims are barred by judicial estoppel (D.I. 86) is denied.
2. Defendants' motion for summary judgment that their invalidity claims are not barred by judicial estoppel (D.I. 98) is granted.
3. Defendants' motion for summary judgment that the claims of the patent in suit are not entitled to the filing date of plaintiffs' 1983 PCT application under the doctrine of judicial estoppel (D.I. 116) is denied.

4. Plaintiffs' motion for summary judgment that they are not estopped from claiming the benefit of the filing date of the 1983 PCT action (D.I. 146) is denied.

Sue L. Robinson

United States District Judge